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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/585,722 LAITENBERGER ET AL. Office Action Summary Examiner Art Unit JACQUELINE WOZNICKI 3774 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 03 December 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-36 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-36 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage

application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

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DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 7, filed 12/03/09, with respect to objections of claims 2-3 have been fully considered and are persuasive. The objection of claims 2-3 have been withdrawn.

Applicant's arguments, see pages 8-9, filed 12/03/09, with respect to 35 U.S.C. 112 rejection of claim 6 has been fully considered and is persuasive. The 35 U.S.C. 112 second paragraph of claim 6 has been withdrawn.

Applicant's arguments filed 12/03/09 have been fully considered but they are not persuasive.

On page 7, Applicants argue that the "envelope" recited in **claim 8** is not a specific structure and is actually "an imaginary reference curve or surface". For this reason, they indicate that the drawing objection should be withdrawn. Examiner respectfully disagrees.

Examiner is one of ordinary skill in the art, and as such, can judge whether a term is "commonly known". Examiner also does not see "envelope" defined within the specification. Furthermore, even if envelope were a commonly known term in the art, it would still need to be pictured as it is mentioned in the claims. As Applicants indicate, the term "axis" is an imaginary reference line through a body. If an "axis" were claimed in the claims and not pictured in the drawings, Examiner would likewise object to the drawings for the axis not being pictured, but mentioned in the claims. Examiner maintains the drawing objection with regards to the "envelope".

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On page 8, Applicants argue that "canceling remainder" is clear because in MRI compatible implants, the aggregate of lobes "cancel" other groups of nodes so there are no eddy currents. Applicants further argue that there are two sets of lobes: "one set" and the "cancelling remainder", and that in view of the specification, the "cancelling remainder" is clear to one of ordinary skill in the art. Examiner respectfully disagrees.

Although "current eddies" and "cancelling remainders" may be in the specification. Examiner is examining the claims. In the claims, it is unclear what "a cancelling remainder of lobes" is. Is it the same as "additional lobes? If so, why is different terminology used? Also, is the "area bounded by the lobes" an area between two sets of lobes? Between the loops? Between a "cancelling remainder" and a crossover point? If Applicant wishes "cancelling remainders" and "area bounded by one set of lobes" to have a clear meaning within claim 4, the claim should be worded similarly to the following example: "The implant according to claim 2, wherein each of said loops has additional loops with additional loop portions formed as additional first lobes and additional second lobes that are different from the first lobe and second lobe, and additional cross-over points between said additional first and second lobes, wherein each additional first and second lobe contains an area, so that in aggregate, the area bounded by the additional first lobes is equal to the area bounded by the additional second lobes." If Applicant wishes to include the reference to "current eddies" in this claim, current pathways within the "additional loops" and "additional first and second lobes" must be referenced as well.

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On page 9, Applicants argue that claim 8 is clear because one of ordinary skill in the art understands that "envelope" is not a specific structure, but is a reference term. Applicants further argue that the drawings illustrate that the loops lie within an envelope transverse to the axis. Examiner respectfully disagrees.

Examiner fails to see any figure with reference a reference term resembling an "envelope" and, as one of ordinary skill in the art, does not believe the explanation provided in Applicant's Remarks is sufficient, without representation in the drawings, to render claim 8 definite and clear. Claims 4 and 8 remain rejected under 35 U.S.C. 112 2nd paragraph.

On pages 9-12, Applicants argue that the point of Pacetti (US 6712844 B2) is to eliminate electrically conductive paths in a typical metal stent, and that in Pacetti there are no conductive loops because they are eliminated by discontinuities. Applicants also argue that the claimed structure from claim 35 is not inherent in Pacetti because the intent is to eliminate the electrically conductive paths present in a typical metal stent. Applicants also argue that Pacetti fails to teach closed loops electrically insulated from each other with a counterpart lobe diametrically opposite on the implant tube (as claimed in claim 35).

Examiner respectfully disagrees. Applicants argue that the "point" of Pacetti is to eliminate electrically conductive paths in a typical metal stent. However, Pacetti states in the Abstract, lines 3-4 that the ultimate goal of the stent is to make the stent easier to image with MRI. Examiner is not sure how this is relevant to the claim objections, as the "point" of Applicant's invention is not listed in the claims, but nevertheless wishes to

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clarify. Examiner also wishes to point out that claim 1, as stated, is anticipated by Pacetti, Applicants say there are no conductive loops. Examiner referenced Column 6. lines 5-8, which clearly states electrically conductive materials, which make up loops (also referenced in the previous office action as item 42, additionally depicted as "loop portions" in Annotated Figure 5). Examiner read the claims as broadly as reasonably possible, which indicate a structure of loops made from a material that is electrically conductive. Pacetti clearly anticipates this limitation. Applicants further argue that the structure from claim 35 is not inherent. Examiner disagrees, as a tubular implant will inherently have a "counterpart" diametrically opposite. Merriam-Webster defines "diametric" as "of, relating to, or constituting a diameter; located at the diameter". As such, a tubular implant has a structure diametrically opposed to it - otherwise it would not be a tube. "a counterpart lobe" is not defined by any sort of structural limitation in claim 35, and so can be assumed to be whatever structure is on that side of the tube. Applicants argue that Pacetti also fails to teach claim 35's limitation that closed loops are electrically insulated from each other with a counterpart lobe diametrically opposite on the implant tube. Examiner wishes to point out that claim 35 does not teach the limitation. Claim 35 refers to a tube that has an electrical conductor having a plurality of loops that are electrically insulated from one another. Although the rest of this claim is unclear (see Claim Objections, below), it does not appear that a counterpart lobe is what isolates each closed loop. Pacetti, however, does teach closed loops (Annotated Figure 5) electrically isolated from each other (Column 7, lines 2-3 indicate that the discontinuities that electrically isolate parts of the metal stent from each other can be

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located in the "connectors" (item 50). This discontinuities being placed there would electrically isolate each loop from the others.). Claims 1-36 remain rejected.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "envelope" mentioned in claim 8 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Objections

Claims 2 and 35 are objected to because of the following informalities: Claim 2 states "figure of eight" but this is grammatically incorrect. It should be worded as "figure eight". Appropriate correction is required. Claim 35 recites "each of said closed loops having a periphery of a string of equal area lobes that are within said closed loops" but this is unclear. What is a "string of equal area lobes"? Where is the "string" pictured? Is the string on the periphery of the closed loops, or does this refer to the periphery of a string? Is it the lobes that are within closed loops? Or is it the string that is within closed loops? Clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, applicant recites a "cancelling remainder" of lobes. It is unclear what a cancelling remainder is and how an area bounded by a set of lobes can equal the area bounded by this.

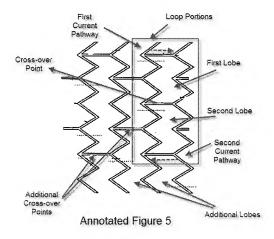
Regarding claim 8, the claim refers to an envelope in line 2, but it is unclear how an envelope fits into this invention.

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Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 11-16, 18-21, 23, 25-29, and 32-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Pacetti (US 6712844 B2).



Regarding claim 1, Pacetti teaches an implant comprising: electricallyconductive (Column 6, lines 5-8) closed loops (Figure 5, item 42) forming an apertured wall (Figure 5) of the implant with an interior volume (Abstract, line 1; a stent is a tube, which has an interior volume), each of said loops being

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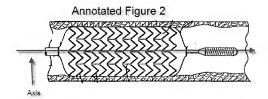
electrically- conductive current pathways (Column 6, lines 5-8) within which eddy currents are liable to be induced when subjected to a time-dependent external magnetic field (Column 6, lines 27-29), each of said loops including a first current pathway and a second current pathway (Annotated Figure 5) wherein said first current pathway and said second current pathway are arranged such that, regardless of the direction of said external magnetic field, the direction of the eddy current that would be induced by said field in said second current pathway is the reverse of the direction of the eddy current that would simultaneously be induced by said field in said first current pathway, thereby to prevent flow of eddy currents in each of said loops (Annotated Figure 5; the directions of the current flowing will be opposite, due to nonconductive connectors present in the loop portion (Column 7, lines 4-7 and 12-14)) (see the Response to Arguments section above).

Regarding claim 2, Pacetti further teaches each of the loops having loop portions (Annotated Figure 5) formed as a first lobe (Annotated Figure 5) and as a second lobe (Annotated Figure 5) of a figure of eight, and further comprises a cross-over point (Annotated Figure 5) between said first lobe and said second lobe

Regarding claim 3, Pacetti further teaches an electrically insulating joint (Column 7, lines 4-7 and 12-14) between said two loop portions at the cross-over

point (Column 7, lines 2-3; the cross-over point as shown in Annotated Figure 5 is located in a connector).

Regarding claim 4, as best understood, Pacetti further teaches each of the loops having additional lobes (Annotated Figure 5) and additional cross-over points between the additional lobes (Annotated Figure 5), with the areas bounded by the lobes being such that, in aggregate, the area bounded by one set of lobes equals the area bounded by a cancelling reminder of the lobes (Figure 2 shows the area represented by the lobes as being symmetrical, and so the area bounded by one will be equal to the another). (See the Response to Arguments section above).



Regarding **claim 5**, Pacetti further teaches the implant having a central longitudinal axis and said interior volume is tubular and centered on said axis (see Annotated Figure 2, above).

Regarding claim 11, Pacetti further teaches the loop portions corresponding to struts that are joined end-to-end to each other (Figure 5, item

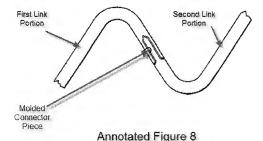
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and can deploy in use to form a zigzag portion (Figure 5; Column 5, lines 48 and can deploy in use to form a zigzag portion (Figure 5; Column 5, lines 48-

Regarding claim 12, Pacetti further teaches the plurality of loops being arranged mutually axially adjacent and spaced along the axis (Figure 2 and Figure 5).

Regarding claim 13, Pacetti further teaches adjacent loops being connected to each other by electrically-insulating links (Column7, lines 2-7 and 12-14).

Regarding **claim 14**, Pacetti further teaches each of the loops including a plurality of electrically-insulating links that connect spaced loop portions of said loop (see the rejection to **claim 13** above, and Annotated Figure 5).



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Regarding claim 15, Pacetti further teaches each link being a mechanical coupling (Figure 8 and Column8, lines 7-9) with a first cooperating link portion (see Annotated Figure 8, above) and a second cooperating link portion (Annotated Figure 8).

Regarding claim 16, Pacetti teaches the cooperating portions being able to move relative to each other (Annotated Figure 8 and Column 8, lines 7-14; the portions will be able to move relative to each other, for example when the stent is being manufactured and the "tongue" portion is placed in the "groove" portion after they have been cut, the two will be "movable" relative to each other).

Regarding claim 18, Pacetti further teaches a layer of bonding material between the cooperating link portions (Annotated Figure 5, Column 7, lines 2-13; adhesive is a bonding material).

Regarding **claim 19**, Pacetti further teaches the bonding material being ceramic (Column 7, lines 38-39).

Regarding **claim 20**, Pacetti further teaches the bonding material being an adhesive composition (Column 7. lines 2-3).

Regarding claim 21, Pacetti further teaches the mechanical coupling comprising interlocking fingers (Figure 8, item 56 and Column 8, lines 7-9).

Regarding claim 23, Pacetti further teaches each link including a molded connector piece (Annotated Figure 8).

Regarding claim 25, Pacetti further teaches the wall of the implant being an apertured tube (Figure 2 and Abstract; a stent is an apertured tube).

Regarding claims 26-27, Pacetti further teaches the implant being made of nickel-titanium shape memory alloy and stainless steel (Column 6, lines 6-7).

Regarding claim 28, Pacetti further teaches the implant being a stent (Abstract).

Regarding claim 29, Pacetti further teaches the stent being radially expansible from a radially compact delivery configuration (Column 5, lines 3-7) to a radially larger deployed configuration (Column 5, lines 26-29) and the stent being capable of being delivered transluminally by a catheter (Figure 1).

Regarding claim 32, Pacetti further teaches the implant being a graft (Column 8, lines 31-32).

Regarding claim 33, Pacetti further teaches the implant being a selfexpanding implant (Column 8, line 36) delivered transluminally in a radially compact configuration (Column 5, lines 3-7) and capable of self-expansion into a radially larger deployed configuration at an implant site (Column 5, lines 26-29).

Regarding **claim 34**, Pacetti further teaches each closed loop exhibiting lobes with an equal lobe area on opposite sides of the interior volume (Annotated Figure 5 and Figure 2).

Regarding claim 35, Pacetti teaches an electrical conductor (Column 6, lines 5-8), said electrical conductor having a plurality of closed loops (Annotated Figure 5 "loop portions") electrically insulated from each other (Column 3, lines 55-57 and Column 7, lines 2-3), each of said closed loops having a periphery of a string of equal area lobes that are within said

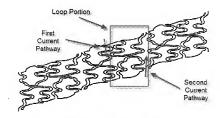
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closed loop (Figure 2). However, Pacetti fails to teach every one of said lobes having a counterpart lobe located diametrically opposite on the implant tube. (see the Response to Arguments section above).

Regarding claim 35 however, it is inherent in the construction of Pacetti's implant that each lobe must have a counterpart lobe located diametrically opposite it on the implant tube. If this was not the case, the current pathways created with the implant is placed under a magnetic field would not cancel each other out, and the implant would not prevent the Faraday Cage effect.

Regarding claim 36, Pacetti further teaches each of the loops having an even number of lobes (Annotated Figure 5; each loop has two lobes).

Claims 1 and 6-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Bucker et al. (WO-03015662 A1; US 20040249440 A1 is being used as a translation thereof).



Annotated Figure 2d

Regarding claim 1, Bucker teaches an implant comprising: electricallyconductive ([0006]; a metallic material is electrically conductive) closed loops (Figures 2a-2e) forming an apertured wall (Figure 1) of the implant with an interior volume (Figure 1), each of said loops being formed from loop portions (see Annotated Figure 2d. above) providing electrically- conductive current pathways ([0006]; a metallic material is electrically conductive) within which eddy currents are liable to be induced when subjected to a timedependent external magnetic field ([0003]), each of said loops including a first current pathway and a second current pathway (Annotated Figure 2d) wherein said first current pathway and said second current pathway are arranged such that, regardless of the direction of said external magnetic field, the direction of the eddy current that would be induced by said field in said second current pathway is the reverse of the direction of the eddy current that would simultaneously be induced by said field in said first current pathway, thereby to prevent flow of eddy currents in each of said loops ([0017]; because the endoprosthesis does not form a closed circuit. current will not flow).

Regarding claims 6-7, as best understood, Bucker further teaches each of the loops wrapping around an axis in the form of a spiral (Figure 4a) with an integral whole number of turns (being at least 3 turns) (Figure 4a; shows 4 turns).

Regarding claim 8, as best understood, Bucker further teaches each of the loops lying within an envelope that is transverse to an axis (Figure 4a; the axis is taken to be the longitudinal axis of symmetry down the center of the lumen of the stent).

Regarding **claim 9**, Bucker further teaches each of the loops wrapping about an axis in a path that spirals around the axis from one end of the implant to the other (Figure 4a).

Regarding claim 10, Bucker further teaches the pitch of the spiral path being constant (Figure 4a).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Raulerson (US 5599311 A).

Regarding claim 17, Pacetti fails to teach the cooperating portions being constituted as a hook portion and an eye to receive the hook portion.

However, Raulerson teaches a hook and eye being used to connect two parts of a stent (Column 7, lines 35-41; Raulerson teaches the equivalence of hook and eye (i.e. Velcro) to interlocking pieces as taught by Pacetti). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the implant as taught by Pacetti with the hook and eye connection as taught by Raulerson because a hook and eye connection would

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allow the strut portions to be removably connectable to each other, but not rigid and immovable, which will increase the flexibility of the stent.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Lenker et al (US 6176875 B1).

Regarding claim 22, Pacetti teaches the mechanical coupling comprising mechanically-engaging surfaces (Annotated Figure 8; "molded connector piece"), but fails to fails to teach them being in combination with at least one restraining strap that overlies the engaging surfaces. However, Lenker teaches restraining straps that lay over the engaging surfaces (Figure 5C and Column 9, lines 44-47) It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the implant as taught by Pacetti with the restraining strap as taught by Lenker because the restraining strap will prevent a self-expanding stent from expanding before a surgeon has delivered the stent to the desired implant position.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Shanley et al. (US 20040122506 A1).

Regarding claim 24, Pacetti teach each link including a portion that is locally thinned with respect to the thickness of the wall of the implant. However, Shanley teaches a portion of connecting struts being thinner than the wall of the implant (Figure 1; item 14 is a connecting strut, which has a width that is thinner

than the struts that comprise the wall of the impant (such as item 22)). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the implant as taught by Pacetti with thin connectors as taught by Shanley so the least amount of material possible will be implanted into a patients body, reducing the likelihood of implant rejection and infection from foreign materials.

Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Tomonto et al. (US 5733326 A)

Regarding claims 30-31, Pacetti fails to teach the implant being a filter or a valve. However, Tomonto teaches the implant being a filter or a valve (Column 3, lines 25-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the stent implant as taught by Pacetti with the embodiments as a filter or valve as taught by Tomonto because the problem solved by Pacetti (preventing the Faraday cage effect when an implant is placed in a magnetic field) would be equally and logically applicable to other implant devices that a doctor might need to see through while a patient is getting an MRI and is exposed to a magnetic field, such as a valve or a filter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE WOZNICKI whose telephone number is (571)270-5603. The examiner can normally be reached on M-R, 9 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul Prebilic/ Primary Examiner, Art Unit 3774

/JACQUELINE WOZNICKI/ Examiner, Art Unit 3774 02/17/10